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Received by fax by SPE. C. Wilder 11/1/2001

CERTIFICATION OF FACSIMILE TRANSMISSION

In re application of

Takahiko, ISHIGURO, et al.

Appln. No. 09/345,761 Group Art Unit: 1655

Confirmation No.: 1618 Examiner: WILDER, C

Filed: July 01, 1999

For: METHOD OF ASSAY OF TARGET NUCLEIC ACID

Commissioner for Patents
Washington, D.C. 20231

Sir:

I hereby certify that this paper Supplemental Amendment is being facsimile transmitted to Examiner C. Wilder at the Patent and Trademark Office on November 1, 2001 at 1 703 308-8724.

Respectfully submitted,

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Date: November 1, 2001 Attorney Docket No.: Q54969

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PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Takahiko, ISHIGURO, et al.

Appln. No.: 09/345,761

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For: METHOD OF ASSAY OF TARGET NUCLEIC ACID

SUPPLEMENTAL AMENDMENT UNDER 37 C.F.R. § 1.111

Commissioner for Patents
Washington, D.C. 20231

Sir:

This Supplemental Amendment is in response to the telephone conversation with Examiner Wilder on November 1, 200. Please amend the above-identified application as follows:

IN THE CLAIMS:

Please enter the following amended claims:

30. A method for assaying for a specific nucleic acid sequence that is within a target RNA, wherein said target RNA is a single-stranded RNA, said method comprising the following steps:

E1

I. providing said target RNA comprising said specific nucleic acid sequence;

II. hybridizing said target RNA to a reagent (A), which is a single-stranded oligo nucleic acid complementary to a sequence 5' of, and adjacent to, the 5' end of said specific

nucleic acid sequence that is within the target RNA, which allows the target RNA to be cut at the 5' end of the specific nucleic acid sequence by the action of a reagent (D), which is a ribonuclease that degrades RNA in a DNA-RNA double-strand;

III. cutting the target RNA at the 5' end of the specific nucleic acid sequence with reagent D to give a product;

IV. hybridizing to said product of step (III), a reagent (B), which is a first single-stranded oligo DNA primer complementary to a sequence at the 3' end of said specific nucleic acid sequence;

V. extending said first single-stranded oligo DNA primer to the 5' end of the specific nucleic acid sequence with a reagent (C), which is an RNA-dependent DNA polymerase and with a reagent (E), which is deoxynucleoside triphosphates, to form a DNA-RNA double-strand;

VI. digesting the RNA strand of said DNA-RNA double-strand from step (V) with the reagent (D), to give a single-stranded DNA complementary to said specific nucleic acid sequence;

VII. hybridizing to said single-stranded DNA from step (VI) a reagent (F) which is a second single-stranded oligo DNA primer having the following sequences, in the following order, beginning at the 5' end and proceeding in a 5' to 3' direction: i) a promoter sequence for a DNA-dependent RNA polymerase, ii) an enhancer sequence for said promoter sequence, and iii) a sequence at the 5' end of said specific nucleic acid sequence;

VIII. extending said second oligo DNA primer to the 5' end of said single-stranded DNA with a reagent (G), which is a DNA-dependent DNA polymerase and with said reagent (E);

IX. synthesizing a single-stranded RNA from said promoter sequence with a reagent (H), which is a DNA-dependent RNA polymerase and a reagent (I), which is ribonucleoside triphosphates;

X. either:

(a) cycling said single-stranded RNA from step (IX) to step (IV), or

(b) hybridizing to said single-stranded RNA from step (IX) a reagent (J), which is a single-stranded oligo DNA complementary to said specific nucleic acid sequence, labeled so that it gives off a measurable fluorescent signal upon hybridization with a nucleic acid containing said specific nucleic acid sequence; and

E1

XI. after addition of reagents (A) to (J), measuring at least once a fluorescent signal from said hybrid formed in step (X) (b);

wherein said reagents (A) to (J) are added to a reaction vessel one by one, in functional combinations, or all at once.

E2

44. The method according to Claim 30, which further comprises a step of detecting or quantifying the target RNA in the sample based on the measured fluorescent signal or change in the measured fluorescent signal.

E3

46. The method according to Claim 30, wherein prior to said step (X)(b)acetate is added as a reagent.

E4 48. The method according to Claim 30, wherein prior to said step (X)(b) sorbitol is added as a reagent.

REMARKS

Claims 30, 44, 46, 48 are all the claims pending in the application.

The claims have been amended editorially to use Roman Numerals instead of Arabic numbers in the steps, to give a letter designation to the reagent referred to in step (7) of claim 30, to clarify in step (3) that reagent D is the reagent used to cut the target RNA as set for the in step 6 of claimed 30, and to clarify that the single stranded RNA referred to in step (1) of claim 30 and in claim 40 is the target RNA.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

Applicant hereby petitions for any extension of time which may be required to maintain the pendency of this case, and any required fee, except for the Issue Fee, for such extension is to be charged to Deposit Account No. 19-4880.

Respectfully submitted,

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